

Claims

1. An anti-HPV-16 E7 antibody obtainable by
 - (a) eliciting an in vivo humoral response against highly purified HPV-16 E7 protein or a fragment thereof in a non-human vertebrate; and
 - (b) affinity-purifying antibodies as obtained in the eliciting-step (a).
2. The anti-HPV-16 E7 antibody of claim 1, wherein said highly purified HPV-16 E7 protein or a fragment thereof is recombinantly produced.
3. The anti-HPV-16 E7 antibody of claim 2, wherein said HPV-16 E7 protein or said fragment thereof is expressed in *E. coli*.
4. The anti-HPV-16 E7 antibody of any one of claims 1 to 3, wherein said highly purified HPV-16 E7 protein or a fragment thereof is purified by a combination of ion exchange chromatography and gel filtration.
5. The anti-HPV-16 E7 antibody of claim 4, wherein said purification further comprises, prior to ion exchange chromatography and gel filtration, a protein precipitation step.
6. The anti-HPV-16 E7 antibody of any one of claims 1 to 5, wherein said affinity purification of the obtained antibodies is carried out over immobilized HPV-16 E7 protein or a fragment thereof.
7. The anti-HPV-16 E7 antibody of claim 6, wherein said HPV-16 E7 protein or a fragment thereof is immobilized on PVDF membranes, nitrocellulose, sepharose, agarose, DEAE-cellulose or DEAE.
8. The anti-HPV-16 E7 antibody of anyone of claims 1 to 7, wherein said non-human vertebrate is selected from the group consisting of rat, mouse, rabbit, chicken, sheep, horse, goat, pig and donkey.

9. Use of an anti-HPV-16 E7 antibody of any one of claims 1 to 8 for the preparation of a diagnostic composition for the (immuno-) histological detection of expressed HPV-16 E7 in a biological sample.
10. The use of any one of claims 9, wherein said (immuno-) histological detection is carried out on Pap-smears, cervical (carcinoma) biopsies, anogenital biopsies, mamma biopsies, head- or neck biopsies or prostate biopsies.
11. The use of claim 9 or 10, wherein said diagnostic composition is used for evaluating the risk of acquiring a sexually transmitted disease or cancer, for measuring the status of an existing sexually transmitted disease or cancer, or for screening therapy efficiency in the treatment of a sexually transmitted disease or cancer.
12. A method for the preparation of a diagnostic composition comprising the step of formulating the anti-HPV-16 E7 antibody of any one of claims 1 to 8 with a diagnostically acceptable carrier, diluent, buffer, or storage solution.
13. The use of any one of claims 9 to 11 or the method of claim 12, wherein said diagnostic composition further comprises suitable means for detection.
14. A diagnostic composition comprising the anti-HPV-16 E7 antibody of any one of claims 1 to 8 or obtained by the method of claim 12 or 13.
15. Kit comprising an anti-HPV-16 E7 of any one of claims 1 to 8, or a diagnostic composition of claim 14.
16. An in vitro method for the detection of a sexually transmittable disease or cancer comprising the steps of
 - a) incubating a biological sample with anti-HPV-16 E7 antibodies of any one of claims 1 to 8; and
 - b) measuring and/or detecting specifically-bound anti-HPV-16 E7 antibodies

whereby the presence, the absence or the amount of specifically-bound anti-HPV-16 E7 antibodies is indicative for said sexually transmittable disease or cancer.

17. The in vitro method of claim 17 further comprising a further step (c), whereby in said step (c) the presence, the absence or the amount of specifically-bound anti-HPV-16 E7 antibodies of step (b) is compared to the presence, the absence or the amount of specifically-bound anti-HPV-16 E7 antibodies in a negative or a positive control sample.
18. Use of an anti-HPV-16 E7 antibody of any one of claims 1 to 8, a diagnostic composition of claim 14 or a kit of claim 15 in an in vitro method for the detection of a sexually transmittable disease or cancer.
19. The in vitro method of claim 16 or 17 or the use of claim 11 or claim 18 wherein said sexually transmitted disease is an HPV16-infection or wherein said cancer is cervical cancer, breast cancer/mamma cancer, prostate cancer, head and neck cancer, penil cancer and/or anogenital cancer/neoplasia (AIN).
20. A method for the production of an anti-HPV-16 E7 antibody comprising the steps of
 - (a) eliciting an in vivo humoral response against highly purified, HPV-16 E7 protein or a fragment thereof in a non-human vertebrate; and
 - (b) affinity-purifying antibodies as obtained in the eliciting-step (a).
21. The anti-HPV-16 E7 antibody of any one of claims 1 to 9 or the method of claim 20, wherein said highly purified HPV-16 E7 protein or said fragment thereof is a native, highly purified HPV-16 E7 protein or a fragment thereof.